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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,286	03/12/2004	Rajagopal Bakthavatchalam	02-090-Z (NEU-02-090-Z)	8664
23520	7590	10/19/2005	EXAMINER WEDDINGTON, KEVIN E	
MAURICE M KLEE 1951 BURR STREET FAIRFIELD, CT 06824			ART UNIT 1614	PAPER NUMBER

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/799,286

Applicant(s)

BAKTHAVATCHALAM ET AL.

Examiner

Kevin E. Weddington

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 186, 187, 199-208 and 217-222 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 186, 199-207 and 217-222 is/are rejected.
- 7) ☒ Claim(s) 187 and 208 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8-22-05</u> . | 6) <input type="checkbox"/> Other: _____ |

Claims 186, 187, 199-208 and 217-222 are presented for examination.

Applicants' amendment and terminal disclaimer filed July 19, 2005; and the information disclosure statement filed August 22, 2005 have been received and entered.

Accordingly, the rejections made under an obviousness-type double patenting and 35 USC 112, first paragraph as set forth in the previous Office action dated April 19, 2005 at pages 2-5 are hereby withdrawn.

Claim Objections

Claims 187 and 208 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 186, 199, 201-203, 205-207 and 217-222 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 99/20589 of PTO-1449, hereby known as Roufogalis et al. or WO 99/09140 of PTO-1449, hereby known as Julius et al.

Roufogalis et al. teach the use of phenylalkanols (ginerol analogues) in the treatment or prophylaxis of pain by action on sensory nerves and/or through anti-inflammatory action (page 1, lines 1-10). Note on page 20, lines 8-38 states the

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gingerol analogues are effective as capsaicin receptor antagonists. Note page 21, lines 1-10 shows the analogues are effective in the treatment of pain and inflammatory conditions.

Julius et al. teach capsaicin receptor-related polypeptides for the treatment of human diseases and painful syndromes such as acute and chronic pain or inflammation (page 11, lines 1-5).

As to the capsaicin receptor antagonist to exhibit no detectable agonist activity in an in vitro assay of capsaicin receptor agonism or is a highly potency capsaicin receptor antagonist in an in vitro assay of capsaicin receptor antagonism, a product of identical chemical composition or compound cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. If the prior art teaches the identical chemical structure, the properties applicants disclose and/or claims are necessary present. (In re Spada, 911F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir., 1990)). In the instant case, the aforesaid high potency in an in vitro assay of capsaicin receptor antagonism and non-detectable agonist activity in an in vitro assay of capsaicin receptor agonism is anticipated by either references, Roufogalis et al. or Julius et al., because each individual reference teaches a capsaicin receptor antagonist possessing the same activity as the instant claims. To treat the various types of pain as disclosed in claims 205-207 and 222 with a capsaicin receptor antagonist is clearly inherent since a pain-relieving compound is known to treat various types of pain and its causes. Clearly, the two cited references anticipate the applicants' instant invention, therefore, the instant invention is unpatentable.

Claims 186, 199, 201-203, 205-207 and 217-222 are not allowed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 200 and 204 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/20589 of PTO-1449, hereby known as Roufogalis et al. or WO 99/09140 of PTO-1449, hereby known as Julius et al.

Roufogalis et al. and Julius et al. were individually discussed above supra for the use of a capsaicin receptor antagonist to treat pain.

The instant invention differ from the cited references in that the cited references do not teach the capsaicin receptor antagonist is administered five times

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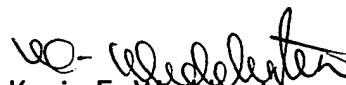
the minimum dose needed to provide analgesia in an adult mammalian is obvious to those skilled in the pharmaceutical art. One skilled in the art would have expected to increase the dose amount to accommodate the size of the adult mammal, for example, a small frame adult may need a lower dose than a large frame adult.

Claims 200 and 204 are not allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin E. Weddington whose telephone number is (571)272-0587. The examiner can normally be reached on 11:00 am-7:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Kevin E. Weddington
Primary Examiner
Art Unit 1614

K. Weddington